K060513

MAR 10 2006

510(k) SUMMARY

Sintea Biotech Posterior Lumbar System Sunflower II
Multi-axial Screw
Prepared February 13, 2006

Trade Name: Sintea Biotech Posterior Lumbar System Multi-axial Screw
Common Name: Spinal Interlaminal Fixation Orthosis
Classification Name(s): Spinal Interlaminal Fixation Orthosis; Spondylolisthesis Spinal Fixation Device System Class II; and Pedicle Screw Spinal System Class II.
Classification(s): § 888.3050 – Spinal Interlaminal Fixation Orthosis; 888.3070 – Spondylolisthesis Spinal Fixation Device System class II; and 888.3070 – Pedicle Screw Spinal System class II.
Device Class: Class II for all requested indications
Classification Panel: Orthopedic Device Panel
Product Code(s): KWP, MNH, MNI

Applicant Name & Address:
Sintea Biotech, Inc.
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Miami Beach, FL 33139
(305) 673-6226 FAX (305) 673-3312

Company Contact:
Mr. Gustavo A. Rios
Sintea Biotech Inc.
407 Lincoln Road
Miami Beach, FL 33139
(305) 673-6226 FAX (305) 673-3312

Predicate Device:
As a special 510(k) submission, the predicate device to which we are claiming equivalence is our own product, Sintea Biotech's **Sintea Biotech Posterior Lumbar System Multi-axial Screw and Recovery Screw with Ring**. This special 510(k) submission represents a modification to the predicate, in that the Sunflower Multi-axial screw has been modified to be a multi-axial screw which holds both 5mm and 5.5mm rods, both rods are within the already FDA cleared range.

Description of Device Modification:
This submission is intended to address a line extension to the Sintea Biotech Posterior Lumbar System. The extension consists of the addition of a multi-axial screw (Sunflower II) which holds 5mm and 5.5mm diameter rods. Both rod diameters are within the already FDA cleared range.

Intended Use and Indications for Use:
The Sintea Biotech Posterior Lumbar System is intended for use in the non-cervical spine.

• As a posterior pedicle screw system: degenerative spondylolisthesis, fracture, dislocation, scoliosis, kyphosis, spinal tumor, pseudarthrosis, severe spondylolisthesis of L5-S1, autogenous bone graft, lumbar/sacral attachment, removal after solid fusion mass develops.

• As a posterior non-pedicle screw system: degenerative disc disease, spinal stenosis, spondylolisthesis, spinal deformities (scoliosis, kyphosis, lordosis), fracture, pseudarthrosis, tumors, unsuccessful previous attempts at spinal fusion.

Device Description:
The PLS Sunflower II screws are available with the same material, shape, fillet, diameters and length of PLS Sunflower screws (K043355). They have the same characteristics as PLS Sunflower Multi-axial screws with the exception that the Sunflower II holds both 5mm and 5.5mm diameter rods instead of only 5mm rods, both sizes fall under an already FDA cleared range.

The locking mechanism of the PLS Sunflower II is the same as the PLS Sunflower Multi-axial screw (K043355) with the exception of the external ring in the locking cap. The external ring in the SUNFLOWER locking cap did not contribute to the mechanical stability of the system, therefore, its absence in the Sunflower II Screw will make the system easier to use intraoperatively.

The PLS Multi-axial Sunflower II screws are made of the same material as the PLS Multi-axial Sunflower screws. The somatic thread is the same as the thread of the PLS standard screws. The lengths and diameters of the multi-axial screws are the same as the lengths and diameters of the PLS standard screws. The design of this screw allows for up to 25 degrees of angulation in any direction to accommodate different anatomic conditions.

Please refer to the body of this submission for an extensive description of the Sunflower II multi-axial screw.

Statement of Technological Comparison:
The subject components share the same materials of construction, intended use and basic design characteristics as the predicate device.

Summary Basis for Equivalence and Comparison Table:
Biomechanical studies conducted on the Sintea Biotech Posterior Lumbar System Sunflower II multi-axial screw implant construct demonstrate that the device system is safe, effective, and suitable for use as a spinal fixation device system. Based on the available information concerning the referenced comparison devices (the Sintea Biotech Posterior Lumbar System), these devices are similar in that:

- The devices have the same intended use and indications for use;
- The devices are made of the same implant alloy; and
- The devices have similar form, function, components, instruments, dimensions, geometry and features.

Performance Standards:
Food and Drug Administration mandated Performance Standards for Spinal Interlaminal Fixation Orthosis, Spondylolisthesis Spinal Fixation Device System Class II, and Pedicle Screw Spinal System Class II devices are not in effect. Sintea Biotech, Inc. intends to comply with all voluntary Performance Standards applicable to the Sintea Biotech Posterior Lumbar System. At the present time, various performance standards such as ASTM, ISO, QSR/GMP and in-house SOP standards are used. Sintea Biotech, Inc. also complies with the general controls authorized under Sections 501, 502, 510, 516, 518, 519 and 520 of the Food, Drug and Cosmetic Act. In addition, Sintea Biotech, Srl., which is the location of the manufacturing facility for this device, has earned the CE Mark (number 0546) using the ISO 9001 quality system model, and is in good standing with IQNet, their international certification body.

Special Controls:
Posterior Lumbar Systems must comply with the following special controls:
(i) Compliance with material standards,
(ii) Compliance with mechanical testing standard,
(iii) Compliance with biocompatibility standard, and
(iv) Labeling which contains the following statements in addition to other appropriate labeling information:

Labeling:
The Sintea Biotech Posterior Lumbar System discussed in this premarket notification will be manufactured by Sintea Biotech, Inc. and labeled as such. The system will be marketed exclusively to healthcare facilities and physicians. In addition, FDA requirements stipulate that the following additional labeling warnings be provided:

Warnings:
• When used as a pedicle screw system, this device system is intended only for grade 3 or 4 spondylolisthesis at the fifth lumbar-first sacral vertebral (L5-S1) vertebral joint.

• The screws of this device system are not intended for insertion into the pedicles to facilitate spinal fusions above the L5-S1 joint.

• Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.

• Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury, and vascular or visceral injury.

• The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

• Precaution: The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

See Warnings and Precautions, and Other Potential Adverse Effects section of the package insert for a complete list of potential risks.

CAUTION: Federal law (USA) restricts these devices to sale by or on the order of a physician.

Surgical Technique:
The surgical approach of the Sintea Biotech Posterior Lumbar System is enclosed in the body of this submission.

CAUTION: Mixing of dissimilar metals can accelerate the corrosion process. The components of this system must NOT be used with implants of other material in building a construct. Components of the Sintea Biotech Posterior Cervical Plates System should NOT be used with components from any other system or manufacturer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 10 2006

Sintea Biotech, Inc.
c/o Mr. Gustavo A. Rios
Product Specialist
407 Lincoln Road, Suite 10L
Miami Beach, Florida 33139

Re: K060513
Trade/Device Name: Sintea Biotech Posterior Lumbar System with Multi-axial Screw
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: KWP, MNH, MNI
Dated: February 13, 2006
Received: February 27, 2006

Dear Mr. Rios:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060513

Device Name: Sintea Biotech Posterior Lumbar System with Multi-axial Screw.

Indications for Use:

The Sintea Posterior Lumbar System is a posterior, nonpedicle screw system of the noncervical spine indicated for degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, fracture, tumor, pseudoarthrosis, and failed previous fusion.

The Sintea Biotech Posterior Lumbar System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The Sintea Biotech Posterior Lumbar System is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-SI vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060513

(Posted February 13th, 2006)